

Serial No. 10/823,089
In re the application of: Varner et al
Page 6 of 8

RECEIVED
CENTRAL FAX CENTER

REMARKS

FEB 20 2007

Claims 62-103 are pending. Claims 82 and 103 are amended. Claims 104-114 are added. Support for the amendments is found throughout the specification as originally filed, and no new matter is added. Reconsideration of the application is respectfully requested.

Claims 82-89, 91, and 103 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenman et al. (US Pat. No. 6,478,776) in view of Rosenwald (US Pat. No. 4,678,466) and claim 90 further in view of Johnson (US Pat. No. 5,972,027). Applicants respectfully traverse.

Applicants recite, in amended claim 82, a method for treating a patient comprising providing a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted; and inserting into a patient ear the device, whereby the device is inserted into the ear through an incision until the cap member abuts the incision, and wherein the body member resides in the patient ear and a therapeutic substance is administered to the patient via the body member.

Applicants recite, in amended claim 103, a method for treating a patient comprising providing a delivery device comprising a therapeutic substance and a non-linear shaped body member having at least two deviations from a linear path and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted; and inserting the device through an incision in a patient ear until the cap member abuts the incision, whereby the body member resides in the patient ear and the therapeutic substance is administered to the patient via the body member.

Serial No. 10/823,089
In re the application of: Varner et al
Page 7 of 8

Rosenman and Rosenwald, alone and in combination, at least fails to teach or suggest (a) a device for insertion into the ear through an incision (i.e. a device for insertion into the ear tissue) and (b) a cap member that abuts an incision through which the device is inserted for stabilizing the device once it is implanted.

Rosenman describes a catheter system and drug delivery structure specifically adapted for insertion into the heart. Rosenman does not teach or even suggest the insertion of such a device into the ear. Further, as shown in Fig. 16, Rosenman's drug delivery structure 12 is implanted within the myocardium so that the proximal tip 38 of the structure 12 is at depth below the endocardial surface 44. Rosenman specifies that this placement is important because it allows the endocardium to heal over the small wound created by implanting the device such that the drug delivery structure will be sealed off from the circulating blood within the heart chamber (See e.g. col. 10 line 62 - col. 11, line 9 and col. 14, line 16- col. 15, line 8). Thus, the head 56 shown in Figs. 18 and 19 situated on the proximal end of Rosenman's drug delivery structure 12 must be of a diameter that is smaller or at most equal to the diameter of the drug delivery structure 12 so that when placed, with the distal end of the structure beneath the endocardial surface, the head 56 is also beneath the surface so that the wound may heal and seal off the device from the circulating blood. That is, the head 56 is not used to stabilize the Rosenman device since it is not configured to remain outside the insertion incision.

Rosenwald does not remedy these deficiencies. Rosenwald describes a medication delivery vehicle that is inserted into channel-like orifices, conduits, or vessels that lead to the particular organ to which medication delivery is sought. The Rosenwald vehicle, as shown in Fig. 1, is provided in a truncated conical shape so that body fluids may pass by it once it is implanted (See e.g., col. 3, lines 56-60). Rosenwald does not teach or even suggest inserting the vehicle into the ear tissue through an incision. In fact, the vehicle is configured specifically to operate within bodily conduits, orifices, vessels and the like (See col. 3, line 48 -line 64), such as the ear canal 50 (Fig. 7; col. 9, lines 14-21). Further, Rosenwald does not teach or suggest a cap member of any type that abuts

Serial No. 10/823,089
In re the application of: Varner et al
Page 8 of 8

an incision through which the device is inserted for stabilizing the device once it is implanted. Rather, according to Rosenwald, the truncated conical shape of the vehicle assures secure retainment of the vehicle in the precise, implanted position. (See e.g. col. 2, lines 60-64; col. 6, lines 15-20)

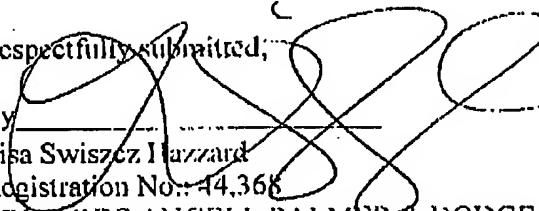
Therefore, even if Rosenman and Rosenwald were combined, the present invention would not be obtained.

In view of the foregoing, it is submitted that each of claims 82 and 103 and all dependent claims are in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

If the Examiner feels that prosecution of the present application can be materially advanced by a telephonic interview, the undersigned would welcome a call at the number listed below.

If for any reason a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge or credit Deposit Account No. 04-1105 under Order No. 56086 C2 (71699).

Dated: February 20, 2007

Respectfully submitted,
By 
Lisa Swiszczyk Hazzard
Registration No. 44,368
EDWARDS ANGELL PALMER & DODGE,
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 439-4444